IN THE CLAIMS:

**Canc l claims 10-26, without disclaimer of their subj ct matter or prejudice to reassertion in this or a continuing application.**

**Amend claims 1-9 to read:**

1. (amended) An isolated polypeptide or a derivative, homologue, analogue, or functional equivalent thereof wherein said polypeptide is obtainable from a species of *Mycobacterium* and which polypeptide is immunointeractive with sera from a human, animal or avian species exposed to said species of *Mycobacterium* or its relative or antigenic parts thereof but which polypeptide is substantially not immunointeractive with sera from a human, animal, or avian species not previously exposed to said species of *Mycobacterium* or its relative or its antigenic parts.

2. (amended) The isolated polypeptide according to claim 1 wherein the species of *Mycobacterium* is selected from *Mycobacterium tuberculosis, Mycobacterium avium, Mycobacterium microti, Mycobacterium leprae, Mycobacterium lepraemurium, Mycobacterium paratuberculosis, Mycobacterium ulcerans, Mycobacterium marinum, Mycobacterium smegmatis, Mycobacterium intracellulare, Mycobacterium xenopi, Mycobacterium chelonei, Mycobacterium fortuitum, Mycobacterium farcinogenes, Mycobacterium flavum, Mycobacterium haemophitum, Mycobacterium kansasii, Mycobacterium phlei, Mycobacterium*

*scrofulaceum, Mycobacterium senegalense, Mycobacterium simiae, Mycobacterium thermoresistible,* and *Mycobacterium xenopi.*

3. (amended) The isolated polypeptide according to claim 2 wherein the species of *Mycobacterium* is *M. tuberculosis.*

4. (amended) An isolated polypeptide or a derivative, homologue, analogue, or functional equivalent thereof wherein said polypeptide is obtainable from *M. tuberculosis* or a related organism and which polypeptide is immunointeractive with sera from a human previously exposed to *M. tuberculosis* or an antigenic extract therefrom but is substantially not immunointeractive with human sera not previously exposed to *M. tuberculosis* or an antigenic extract thereof.

5. (amended) The isolated polypeptide according to claim 4 wherein the human exposed to *M. tuberculosis* has active pulmonary or extra-pulmonary tuberculosis.

6. (amended) The isolated polypeptide according to claim 4 or 5 wherein the polypeptide has a molecular weight of from about 5 kDa to about 100 kDa.

7. (amended) The isolated polypeptide according to claim 6 wherein the molecular weight is selected from about 10 to 20 kDa, 28 to 38 kDa, 38 to 48 kDa, 53 to 63 kDa, and 55 to 65 kDa.

8. (amended) An isolated polypeptide comprising an amino acid sequence selected from SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, or an amino acid sequence having at least 60% similarity to any one of said sequences.

9. (amended) An isolated polypeptide encoded by a nucleotide sequence selected from SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:9, or a nucleotide sequence having at least 60% similarity to any one of said sequences or a nucleotide sequence capable of hybridizing to any one of said sequences under low stringency conditions at 42°C.

## REMARKS

This is in response to the Office Action that was mailed on January 17, 2001. Claims 1-9 are in the case.

The sequence identifiers in the specification have been amended as required by the Examiner.

Claims 1-7 were rejected under the second paragraph of 35 USC 112, the Examiner questioning the definiteness of the term "substantially" in the phrase "substantially not immunointeractive with human sera". One skilled in the art

would have no difficulty in determining whether a particular polypeptide was substantially not immunointeractive with human sera in the sense of the present claims. In any case, Applicants provide extensive guidance for determining the substantial absence of immunointeractive, for instance in the specification, from line 10 on page 22 through line 29 on page 24. See also Example 8 on pages 34-36 of the specification. In order to further clarify this point, Applicants present in the IMMUNO-REACTIVITIES APPENDIX extensive data relating thereto. Finally, Applicants also enclose a copy of their article "Cloning and expression of Immunoreactive Antigens from *Mycobacterium tuberculosis*", Clinical and Diagnostic Laboratory Immunology, July 2000, pp. 600-606. It is respectfully submitted that – considering the level of skill of the persons for whom the present application is written – the claims in their present form satisfy the requirements of the statute.

Claims 8 and 9 were rejected under the second paragraph of 35 USC 112, due to their form of identifying sequences. The claims have been amended to conform to current USPTO practice, thus obviating the rejection.

Claims 1-7 were rejected under 35 USC 102(b) as being anticipated by the Thybo article. The rejection is respectfully traversed. Thybo is concerned with serodiagnosis as such. The present invention provides new markers for use in serodiagnosis of TB. Thus, the present claims relate to the immuno-reactivity of antigens for TB, whereas the aim of Thybo's study was "to evaluate the value of serodiagnosis of TB by ELISA in an HIV and TB endemic region" (p. 153). In any case, as can be seen from the "totals" rows in Tybo, the controls

had antigen titers averaging 0.70 (0.68 + 0.72 / 2) as compared to antigen titers for Tybo's polypeptide averaging 1.15 (1.03 + 1.26 / 2). An antigen titer of 0.70 does not meet the present claims' requirement "which polypeptide is substantially not immunointeractive with sera from a human, animal or avian species not prior exposed to said species of *Mycobacterium* or its relative or its antigenic parts". Accordingly the present claims are not anticipated by Thybo.

**Conclusion**

It is believed that a full and complete response has been made to the Office Action, and that as such, the Examiner is respectfully requested to send the application to Issue.

In the event there are any matters remaining in this application, the Examiner is invited to contact Mr. Richard J. Gallagher, Registration No. 28,781 at (703) 205-8000 in the Washington, D.C. area.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a two (2) month extension of time for filing a response in connection with the present application and the required fee of $390.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit

Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Enclosures: Marked Up Version of Amendments
Immuno-reactivities appendix
Lim et al. article